

SMALL BUSINESS INNOVATION RESEARCH PROGRAM

RELEASE DATE: August 3, 2004

NOTICE: NOT-OD-04-055

National Institutes of Health (NIH)
Centers for Disease Control and Prevention (CDC)

Contract Proposal Receipt Date: November 5, 2004

Innovative technologies and methodologies fuel progress in biomedical and behavioral research and represent an increasingly important area of the economy. The Small Business Innovation Research (SBIR) program provides support for research and development (R&D) of new or improved technologies and methodologies that have the potential to succeed as commercial products.

The purpose of this notice is to (1) announce the issuance of the SOLICITATION OF THE PUBLIC HEALTH SERVICE FOR SMALL BUSINESS INNOVATION RESEARCH CONTRACT PROPOSALS (PHS 2005-1) with a due date of NOVEMBER 5, 2004 for receipt of SBIR CONTRACT proposals; and (2) inform the public about the opportunities that the SBIR program offers to small business concerns as well as to scientists at research institutions. The SBIR legislation requires the Public Health Service (PHS), Department of Health and Human Services, and certain other federal agencies to reserve 2.5 percent of their extramural research or R&D budgets for an SBIR program. The PHS SBIR set-aside requirement for FY 2004 is \$563 million.

The offeror organization must be a small business concern as defined by the Small Business Administration and described in the Solicitation, and the PRIMARY EMPLOYMENT of the principal investigator MUST be with the small business concern at the time of award and during the conduct of the proposed project. In accord with the intent of the SBIR program to increase private sector commercialization of innovations derived from federal R&D, scientists at research institutions can play an important role in an SBIR project by serving as consultants and/or subcontractors to the small business concern. Generally, one-third of the Phase I budget may be spent on consultant and/or subcontractual costs, and, generally, one-half of the Phase II budget may be spent on such costs. In this manner, a small business concern with limited expertise and/or research facilities may benefit from teaming with a Scientist(s) at a research institution; for the scientist(s) at a research institution, this team effort provides support for R&D not otherwise obtained.

The SBIR program consists of the following three phases:

PHASE I: The objective of this phase is to determine the scientific and technical merit and feasibility and potential for commercialization of the proposed research or R&D

efforts and the quality of performance of the small business concern, before consideration of further federal support in Phase II. Generally, Phase I SBIR awards do not exceed \$100,000 for direct costs, Facilities and Administrative (F&A) costs, and negotiated fixed fee for a period generally not to exceed six months.

PHASE II: The objective of this phase is to continue the research or R&D efforts initiated in Phase I. Funding shall be based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II proposal. Only Phase I contractors are eligible to apply for Phase II funding, and Phase II proposals may be submitted upon the request of the Contracting Officer ONLY. (However, see "Fast-Track" Initiative below.) Generally, Phase II awards do not exceed \$750,000 for direct costs, F&A costs, and negotiated fixed fee for a period generally not to exceed two years. That is, generally, a two-year Phase II project does not cost more than \$750,000 for that project. Only one Phase II award may be made for any SBIR project.

PHASE III: The objective of this phase is for the small business concern to pursue, with non-SBIR funds, the commercialization of the results of the research or R&D funded in Phases I and II.

"FAST-TRACK" INITIATIVE: (Applicable only to proposals submitted to the National Institutes of Health [NIH] and only if an awarding component indicates it is accepting Fast Track proposals for a particular topic.)

The Fast-Track initiative is an opportunity for small business concerns to submit both a Phase I and Phase II proposal for concurrent peer review. This initiative also has the potential to minimize any funding gap between Phase I and Phase II. Proposals must be prepared in accordance with Phase I and Phase II proposal preparation instructions.

Following are the research topics contained in the SOLICITATION OF THE PUBLIC HEALTH SERVICE FOR SMALL BUSINESS INNOVATION RESEARCH CONTRACT PROPOSALS (PHS 2005-1) for the contract proposal RECEIPT DATE of NOVEMBER 5, 2004:

NATIONAL INSTITUTES OF HEALTH

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

- o 017 Development of Methodology for Measuring Compliance for Medications
- o 026 Science Education Materials Development for Kindergarten through 12th Grade
- o 027 Development and Clinical Testing of Biochemical Markers

National Cancer Institute (NCI)

- o 195 Virtual Microscopy for the Early Detection of Cancer

- o 196 Antibody Array for Cancer Detection
- o 197 Early Detection Research Network Bioinformatics Research Program (EDRN-BRP)
- o 198 Chemical Optimization and Structure-Activity Relationships
- o 203 Development of a Database and Candidate Gene, Protein, and Biochemical Pathway Nomination Software for Tobacco-Related Disease and Tobacco Addiction Investigations
- o 204 Plant Genomic Models for Establishing Physiological Relevance of Bioactive Components as Cancer Protectants
- o 205 Metabolomics for Early Cancer Detection
- o 206 Methods for Innovative Pharmaceutical Manufacturing and Quality Assurance
- o 207 Synthesis Modules for Radiopharmaceutical Production
- o 208 Targetry Systems for Production of Research Radionuclides
- o 209 Establishment of Benchmark Data Sets for Radiotherapy Quality Assurance
- o 210 Using Social Marketing to Disseminate Evidence-based Energy Balance Intervention Approaches to Worksites
- o 211 Developing Item Response Theory Software for Outcomes and Behavioral Measurement
- o 212 Integrating Patient-Reported Outcomes in Clinical Oncology Practice
- o 213 Portable e-Technology Tools For Real-Time Energy Balance Research
- o 214 Systems to Enhance Data Collection and Medication Compliance in Clinical Trials

National Institute on Drug Abuse (NIDA)

- o 028 Prevention Training
- o 029 Development of Science Education Materials or Programs
- o 060 Develop New Technologies for Screening and Assessing Drug Abuse and Matching Patients with Appropriate Treatment Services

- o 065 Development of New Chemical Probes and Discovery of Alternate Drug Delivery Dosage Forms for Drug Abuse Studies
- o 067 Development of Novel Approaches in Human Neuroscience
- o 070 Develop Research Training Modules for International Application
- o 071 Microarray Technology Applications in Drug Abuse and Addiction
- o 072 Medicinal Chemistry - Design and Synthesis of Novel Chemical Libraries for Treatment Agents for Drug Abuse
- o 073 Internet-based Application of Existing/Proven Therapies
- o 074 Development of Cell-Based Assays to Identify Therapeutic Targets for Substance Abuse and Addiction
- o 075 Real-time Data Collection Paired with Ecological Momentary Assessment (EMA)

National Institute of Mental Health (NIMH)

- o 045 Suicide Prevention Materials and Training for Criminal and Civil Court Systems (Adult/Geriatric/Child and Adolescent Populations)
- o 055 Development of Tools to Enhance Mental Health Interventions and Services Research Training: Executive Research Leadership or Science/Research Education Curriculum

National Heart, Lung, and Blood Institute (NHLBI)

- o 031 New Technology Development for Global Assay of Blood Coagulation
- o 032 Bioreactor Production of Clinical Grade rAAV in Sf9 Cells for DMD

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

National Center for HIV, STD AND TB Prevention (NCHSTP)

- o 021 Development of a Novel Internet-Based Information System for Remote TB Control and Prevention Programs

National Center for Environmental Health (NCEH)

- o 014 Unmanned Aerial Vehicle and Imagery for Humanitarian Response

- o 015 Automated User Defined Tool for Emergency Planning and Quality Control

National Immunization Program (NIP)

- o 016 Develop Methods to Enhance Administration of Vaccines, Including Live Virus Vaccines, Through the Respiratory Tract

- o 019 Disposable-Cartridge Jet Injector Technology

National Center for Infectious Diseases (NCID)

- o 033 Development of Serologic Assays to Measure Immune Responses in Anthrax
- o 034 Biological Control of Lyme Disease Spirochete Vector Ticks
- o 035 Oral Vaccines that Target Peridomiliary Lyme Disease Reservoirs
- o 036 Murine Monoclonal Antibody/Human IgM Chimeric Antibody Construction and Expression
- o 037 Vaccination of Birds for West Nile Virus Using Recombinant Seeds
- o 038 Development of Novel Reagents for Poxvirus Research and Diagnostics
- o 039 North American Orthopoxviruses as Vaccine Vectors: Safety, Efficacy and Feasibility
- o 040 Assay Development for Taenia solium Cysticercosis and Taeniasis

National Center on Birth Defects and Developmental Disabilities (NCBDDD)

- o 001 Development of Materials for "Birth Defects Prevention Month"
- o 002 Development of Health Communication Materials to Prevent Alcohol-Exposed Pregnancies in Underserved Populations
- o 003 Development, Production, and Evaluation of a Folic Acid Educational Tool for Use with a Variety of Audiences
- o 004 Teratogen Symbol Testing among Diverse Audiences
- o 005 Development of Health Education Materials to Promote Pre-Pregnancy Health Visits

INQUIRIES

Eligibility requirements, definitions, submission procedures, review considerations, contract proposal forms and instructions, and other pertinent information, including the "Fast-Track" Initiative, are contained in the SOLICITATION OF THE PUBLIC HEALTH SERVICE FOR SMALL BUSINESS INNOVATION RESEARCH CONTRACT PROPOSALS (PHS 2005-1) for the proposal receipt date of November 5, 2004. The PHS SBIR Contract Solicitation PHS 2005-1, including proposal forms, is available electronically through the National Institutes of Health's "Small Business Funding Opportunities" home page at <http://grants.nih.gov/grants/funding/sbir.htm>. See SBIR Phase I

Contract Solicitation PHS 2005-1 (PDF

[<http://grants.nih.gov/grants/funding/SBIRContract2005/PHS2005-1.pdf>]

or MS Word

[<http://grants.nih.gov/grants/funding/SBIRContract2005/PHS2005-1.doc>]).

Be sure to use the appropriate CONTRACT PROPOSAL forms as they differ from the PHS 398 GRANT application forms.

Note: The SBIR Phase I Contract Solicitation will only be available via electronic means. Potential offerors are encouraged to check the NIH SBIR/STTR home page for updates on the program. Any updates or corrections to the solicitation will be posted there.

Contracting Officers

Any small business concern that intends to submit an SBIR contract proposal under this Solicitation should provide the appropriate contracting officer(s) with early, written notice of its intent, giving its name, address, telephone, and topic number(s). If a topic is modified or canceled before this Solicitation closes, only those companies that have expressed such intent will be notified.

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CENTERS FOR DISEASE CONTROL AND PREVENTION

National Center for HIV, STD, and TB Prevention (NCHSTP)
National Center for Environmental Health (NCEH)
National Immunization Program (NIP)
National Center for Infectious Diseases (NCID)
National Center on Birth Defects and Developmental Disabilities (NCBDDD)

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Those interested in the PHS SBIR/STTR GRANT program may access electronically (<http://grants.nih.gov/grants/funding/sbir.htm>) the OMNIBUS SOLICITATION OF THE PUBLIC HEALTH SERVICE FOR SMALL BUSINESS INNOVATION RESEARCH (SBIR) and SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) GRANT APPLICATIONS (PHS 2004-2). There is one GRANT APPLICATION receipt date (December 1, 2004) remaining for calendar year 2004.

To better understand the differences between grants and contracts, see http://grants.nih.gov/grants/funding/contracts_vs_grants.htm.

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